

**USSN 09/717,478**  
**ANDERSON et al.**  
**AMENDMENT AND RESPONSE**

**REMARKS**

Any fees that may be due in connection with this response may be charged to Deposit Account 50-1213. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Attention is directed to the patent of Howard III, U.S. Patent No. 5,408,535, to the patent by Van Deusen et al., U.S. Patent No. 5,132,097, and to the patent by Augstein, U.S. Patent No. 5,665,310, which were cited in the Information Disclosure Statement mailed March 7, 2001.

Claims 1-9 and 11-30 are pending in this application. Claims 1-9 and 11-14 are amended herein. Claim 10 is cancelled, and claims 15-29 are added herein. The claims are amended to correct minor language inconsistencies, and in order to more particularly point out and distinctly claim the subject matter that applicants regard as the invention. No new matter has been added nor are the amendments intended to alter the scope of the claims or to avoid any cited art. Claim 10 is cancelled herein because it appears to be duplicative of claim 1. Claim 1 is amended to indicate that the surface of the test strip is uniformly illuminated. Basis for this amendment is found in the specification, for example, at page 40, lines 22-24, and page 42, lines 7-11.

Claims 16-30, which are added herein, find basis throughout the specification. For example, particular basis for claims 16-18 can be found, for example, at page 46, lines 19-25 and in original claim 1. Particular basis for claim 20, which recites in part that light is transmitted onto the surface at an angle normal to the surface, and light reflected normally from the surface is measured, can be found, for example, in original claim 1 and in the specification, for example, at page 45, lines 2-5. Particular basis for claim 21, which is directed to a method for reading a surface of a test strip, and recites in part that the reader head is directed to a plurality of positions over the test strip, is found, for example, at page 46, lines 8-27. Particular basis for claim 22 can be found, for example, at page 45, lines 17-18. Particular basis for claim 23 and 24, can

**USSN 09/717,478**  
**ANDERSON et al.**  
**AMENDMENT AND RESPONSE**

be found, for example, at page 45, lines 24-26 and at page 45, lines 27-29, respectively. Particular basis for claim 25, which is directed to a method for reading a surface of a test strip, where measuring the first amount of light is used to determine an amount of background light, can be found, for example, at page 45, lines 13-17. Particular basis for claim 26, which is directed to a method for reading a surface of a test strip, where measuring the third amount of light is used to detect a symbology or the presence of an analyte on the test strip, can be found, for example, at page 45, lines 27-29.

Particular basis for claim 27 can be found, for example, at page 31, lines 17-20, particular basis for claim 28, which is directed to a method for reading a surface of a test strip, and including one or more steps of analysis of the light measurements, can be found, for example, at page 49, line 17, to page 49, line 2, and at page 56, lines 3-7, and at page 60, lines 26-30. Particular basis for claims 29 and 30, can be found, for example, at page 43, line 20 through page 44, line 2, and at page 44, line 27, through page 45, line 7. Therefore, no new matter is added.

Figure 3 is amended to more clearly indicate the components of immunoassay device 300, and also to indicate the test strip therein. Support for the amendment to Figure 3 is found in Figure 2B.

The specification is amended to identify components of immunoassay device 300 not previously identified. Support for the amendment identifying components 306, 308, 310 and 312 of immunoassay device 300 is found in the specification, for example, at page 66, lines 15-30, which defines the analogous components 206, 208, 210 and 212 for immunoassay device 200.

Included as an attachment is a marked-up version of the specification paragraph and the claims that are being amended, per 37 C.F.R. § 1.121.

**USSN 09/717,478  
ANDERSON *et al.*  
AMENDMENT AND RESPONSE**

A further Information Disclosure Statement is filed herewith. Acknowledgement of receipt and consideration of these references are respectfully requested.

Formal drawings reflecting the corrections noted herein have been filed under separate cover.

**OBJECTION TO THE DRAWINGS**

The drawings are objected to as containing numbered components not identified in the specification and as not containing numbered components discussed in the specification. Applicants have provided a new Figure 3, which identifies test strip 100 and other components which are also identified in the specification and Figure 2B. Applicants have also amended the specification to identify numbered components 304, 306, 308 and 310, which were not previously identified in the specification, as amended. Accordingly, Applicants submit that the specification now identifies all numbered components in the Figures and that all numbered components discussed in the specification are also identified in the Figures.

**THE REJECTIONS OF CLAIMS 1-3, 5-6 and 9-15 UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 1-3, 5-6, 9 and 13-14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. Bases for rejection are discussed below. Reconsideration of the grounds for this rejection is respectfully requested in view of the amendments herein and the following remarks.

1. Claims are amended herein to conform to the requirements for proper antecedent basis and to more clearly indicate the subject matter that applicants regard as the invention. These amendments do not change the intended scope of the claims nor avoid any art of record, but merely address minor informalities noted by the Examiner.

**USSN 09/717,478**  
**ANDERSON et al.**  
**AMENDMENT AND RESPONSE**

**2. Rejection of Claims 5, 11 and 12 for Reciting "Substantially"**

Claims 5, 11 and 12 are rejected under 35 U.S.C. §112, second paragraph, because the term "substantially" recited in these claims allegedly renders the claim indefinite. Claim 11 is amended to no longer recite the term "substantially", rendering this ground of rejection moot. Applicants respectfully traverse this ground for rejection to the extent it applies to claims 5 and 12. It is respectfully submitted that for claims 5 and 12, the term "substantially" in the context of these claims and when read in light of the specification (see "Relevant Law" and "Analysis" below) does not render these claims indefinite.

**Relevant Law**

Claims are considered in light of the specification and the general understanding of the skilled artisan. *Rosemount Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547, 221 USPQ 1, 7 (Fed. Cir. 1984), *Caterpillar Tractor Co. v. Berco, S.P.A.*, 714 F.2d 1110, 1116, 219 USPQ 185, 188 (Fed. Cir. 1983). When one skilled in the art would understand all of the language in the claims when read in light of the specification, a claim is not indefinite.

35 U.S.C. § 112, second paragraph requires only reasonable precision in delineating the bounds of the claimed invention. Claim language is satisfactory if it reasonably apprises those of skill in the art of the bounds of the claimed invention and is as precise as the subject matter permits. *Shatterproof Glass Corp. v. Libby-Owens Ford Col.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir.), cert. dismissed, 106 S.Ct. 340 (1985).

In particular, a claim phrase containing the term "substantially" does not stand in a vacuum. When the specification teaches how the claim element is formed in order to provide the desired effect, use of the term "substantially" does not render the claim indefinite. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The limitation "substantially" is definite when, in the light of the specification, one of skill in the art would know what is meant by the term,

**USSN 09/717,478**  
**ANDERSON et al.**  
**AMENDMENT AND RESPONSE**

even if additional experimentation were needed. *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

It is respectfully submitted that in this instance, the skilled artisan would know what is meant by the term "substantially."

**Analysis**

**Claim 5: Substantially Co-Planar Relationship**

The specification teaches how fiber optic conductor ends can be formed to be in a "substantially co-planar relationship", and also teaches effects resultant from fiberoptic conductor ends formed in a substantially co-planar relationship. For example, the specification provides, at page 41, lines 1-17, a method for forming a reader head containing fiber optic bundles. This process includes setting fiberoptic conductors in a resin at the reader head aperture and trimming the fiberoptic conductors flush with the aperture so as to define a planar surface. Further, the specification teaches, for example, at page 44, lines 12-18, that the fiberoptic conductor ends are co-planar at the aperture when the reader head is positioned to take measurements. The specification also teaches, for example, at page 41, lines 18-24, that by forming a planar surface of fiberoptic conductor ends, efficient transfer of light to and from the fiberoptic conductor ends is achieved. The specification thereby clearly defines and indicates what is meant by "substantially co-planar."

In view of the teachings in the specification, it is respectfully submitted that one skilled in the art would understand the formation and effect of fiberoptic conductor ends arranged in a "substantially co-planar relationship" and, accordingly, would know what is meant by this term.

**Claim 12: Reflect Substantially Optimally**

The specification teaches selection of LEDs of any of a variety of wavelengths and the effects resultant from the selected wavelength that "reflect[s] substantially optimally." For example, the specification teaches, at page 43, lines 6-13 that all detectable electromagnetic wavelengths can be

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

selected. Further, the specification teaches, for example, at page 43, lines 15-19 that the wavelength is selected to allow removal of background effects and to optimize reading of a reduction in reflectance at the reaction regions of the test strip. Therefore, It is respectfully submitted that one skilled in the art would understand from the teachings in the specification how to select a wavelength that "reflect[s] substantially optimally" from a test region of a test strip and, accordingly, would know what is meant by this term.

**3. Rejection of Claim 15 for Reciting "Stripe"**

Claim 15 is rejected for reciting a "stripe" which the Office Action alleges is vague and indefinite. This rejection is respectfully traversed. It is respectfully submitted that one skilled in the art would understand the meaning of "stripe" in light of the specification. For example, the specification teaches one skilled in the art methods for forming a stripe and representative dimensions of a stripe. The specification teaches, for example at page 69, line 26, through page 70, line 12, that antibodies can be applied to a test strip using an IVEK Linear Stripper. The antibodies can be used, for example, to bind an analyte of interest, such as a labeled antibody (page 24, lines 4-7). When an antibody-analyte complex is bound by an immobilized antibody in the stripe, a colored stripe can be formed (page 29, lines 25-28). The specification, at page 70, lines 4-5, provides that an exemplary stripe can have dimensions that are approximately 7.5 mm (wide) x 0.5-1.0 mm (high). In sum, the specification teaches one skilled in the art exemplary methods of creating a stripe and exemplary dimensions of a stripe and clearly describes a stripe. Accordingly, It is respectfully submitted that, in view of the teachings of the specification, one skilled in the art would understand the meaning of the term "stripe" as recited in claim 15.

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

**THE REJECTION OF CLAIMS 1, 3-4 and 8-10 UNDER 35 U.S.C. §102(a)**

Claims 1, 3-4 and 8-10 are rejected under 35 U.S.C. §102(a) as being anticipated by Connolly International PCT application No. WO96/13707, which allegedly discloses an assay apparatus for determining color of a test strip at multiple wavelengths, and software for analyzing the results. This rejection is respectfully traversed insofar as it applies to the rejected claims and any presently pending claims.

**Relevant law**

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. In re Spada, 15 USPQ2d 1655 (Fed. Cir., 1990), In re Bond, 15 USPQ 1566 (Fed. Cir. 1990), Soundscriber Corp. v. U.S. 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. See, also, Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.), cert. denied, 110 S.Ct. 154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention". In re Lang, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Moreover, it is incumbent on Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. Lindemann Maschinen-fabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, the reference must describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. An inherent property has to flow naturally from what is taught in a reference In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

**The claims**

Claim 1 specifies a method for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface having the image, uniformly illuminating the surface with light of a

**USSN 09/717,478**  
**ANDERSON et al.**  
**AMENDMENT AND RESPONSE**

first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface. Dependent claims 3, 4, 8 and 9 specify various embodiments; claim 10 is cancelled herein.

**Connolly**

Connolly discloses a diagnostic test strip for use in an analyzer for measuring analyte in a sample. The test strip includes an elongate body having first and second ends and a hinged portion between the ends so that the first end is foldable over the second end or the body. The first and second ends each have an opening aligned with each other when the first end is folded. A carrier layer means includes a separating layer for whole blood cells.

The density of a color reaction is determined using a spectrophotometric device that includes a hand-held housing, a test strip holding region that is located above three light detectors or sensors each disposed within a port. During test operation, a test strip is inserted into the holding region so that the test strip openings are located adjacent to the ports. Light sensors take a reading from the exposed portions of the strip. In operation, as a test strip is inserted into the device, the instrument detects a change in the exposed portion and identifies the test type by reading a color coded label. A sample is then applied and the measurement cycle commences. The instrument measures the density of the reaction and determines the concentration.

The method of Connolly does not entail moving a reader head over the surface of the test strip. Moreover, Connolly does not teach or suggest a method that includes moving the reader head in a reflectance reader over the surface of a test strip.

**Analysis**

The method for reading the surface of a test strip disclosed by Connolly does not include a step of moving a reader head over the surface of a test strip

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

as required by the instantly claims. Accordingly, Connolly does not disclose each element of claim 1 or a claim dependent therefrom, nor each element of any of the presently pending claims. Therefore, Connolly does not anticipate any of the instant claims.

**THE REJECTIONS OF CLAIMS 2, 5-7 and 11-15 UNDER 35 U.S.C. §103**

**Relevant law**

To establish a *prima facie* case of obviousness, prior art references when combined must teach or suggest all the claim limitations. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). When the elements of an underlying independent claim is not taught or suggested by a first reference, *prima facie* obviousness for a claim dependent therefrom cannot be established by additional prior art that merely teaches or suggests the particular limitation recited in the language of the dependant claim. *In re Royka*, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974).

**THE REJECTION OF CLAIMS 2, 5-7 and 11-12 UNDER 35 U.S.C. §103(a)**

Claims 2, 5-7, 11 and 12 are rejected under 35 U.S.C. §103 as being unpatentable over Connolly and Henicz because Connolly allegedly anticipates claim 1, and Henicz teaches a read head with an aperture and use of fiberoptic bundles to illuminate a sample and measure reflected light. This rejection is respectfully traversed.

**Claims**

Claims 2 and 5 are directed to the method of claim 1 where the reader head contains elements including a light emitting diode, a fiberoptic bundle coupled to the light emitting diode, an aperture, and fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture. Claims 6 and 7 are dependent from claim 5. Claim 11 is directed to the method of claim 1, where light of a first wavelength reflects equally from all regions of the test strip.

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

Claim 12 is directed to the method of claim 1, where light of a second wavelength reflects substantially optimally from a test region of the test strip.

**Hernicz**

Hernicz teaches a reader head with reduced height sensitivity that measures reflectance from a sample. The reader head is configured such that the upper portion of the inner surface is hemispherically shaped and the lower portion is conically shaped. In the method of Hernicz, a sample is exposed to light from a high intensity flash lamp or continuous incandescent lamp and two fiber optic bundles (one sample and one reference) receive reflected light and transfer the light to a pair of detectors. Hernicz does not teach or suggest moving a reader over the surface of a test strip.

Hernicz does not teach or suggest use of a fiber optic bundle optically coupled to a light emitting diode. Hernicz further does not teach or suggest a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture. Hernicz does not teach or suggest light of a first wavelength reflecting equally from all regions of a test strip. Connolly also does not teach or suggest a fiber optic bundle optically coupled to a light emitting diode, a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, or a first wavelength reflecting equally from all regions of a test strip.

**Analysis**

It is respectfully submitted that a *prima facie* rejection of these claims has not been established as the combination of teachings of the cited references does not teach or suggest all the claim limitations nor result in the instantly claimed methods. As discussed above, the method of Connolly does not include moving a reader head over the surface of the test strip. Accordingly, Connolly does not teach or suggest a method that includes moving the reader head in a reflectance reader over the surface of a test strip. Hernicz, which does not teach or suggest a method in which a reader head scans a surface, does not cure the defects in the teachings of Connolly. The teachings of the

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

references, when combined, cannot establish the method of claim 1 as *prima facie* obvious because the references do not teach or suggest all elements of the claims. Accordingly, the combination of teachings of Connolly and Hernicz does not result in any of claims 2, 5-7, 11 and 12. Therefore, *prima facie* case obviousness has not been established.

Claims 2 and 5, and claims dependent therefrom, are further unobvious over Connolly and Hernicz as neither of the cited references teaches or suggests a method that uses a reader head the contains a fiber optic bundle optically coupled to a light emitting diode or a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture.

Claim 11 is further unobvious over Connolly and Hernicz as neither of the cited references teaches or suggests light of a first wavelength reflecting equally from all regions of a test strip. In fact, Hernicz teaches away from claim 11 by teaching that light containing no quantitative or concentration sample information is to be avoided (column 5, lines 1-5).

**THE REJECTION OF CLAIMS 13 and 15 UNDER 35 U.S.C. §103(a)**

Claims 13 and 15 are rejected under 35 U.S.C. §103 as being unpatentable over Connolly and Senyei (International PCT application No. WO92/10585) because Connolly allegedly teaches all of the limitations of claim 1, and Senyei allegedly teaches detecting fetal fibronectin and use of a test strip with spots indicating test results. This rejection is respectfully traversed.

**Claims**

Claim 13 recites that the analyte is fetal fibronectin.

Claim 15 recites that the image is a stripe.

**Senyei**

Senyei teaches methods for determining the status of a pregnancy by detecting the presence of a fetal restricted antigen such as fetal fibronectin. Senyei does not teach or suggest a moving a reader head over the surface of a test strip, and, thus, does not cure the defects in the teachings of Connolly.

**USSN 09/717,478  
ANDERSON *et al.*  
AMENDMENT AND RESPONSE**

**Analysis**

Neither Connolly nor Senyei teaches or suggests moving a reader head over the surface of a test strip (or moving a test strip across a read head). Thus, when combined, the cited references cannot establish claim 1 as *prima facie* obvious. Accordingly, the combination of Connolly and Senyei cannot establish claims 13 and 15, which are dependent from claim 1, as *prima facie* obvious.

**THE REJECTION OF CLAIM 14 UNDER 35 U.S.C. §103(a)**

Claim 14 is rejected as being unpatentable over Connolly, Hernicz and Senyei because Connolly and Senyei allegedly teach all of the limitations of claim 5 and Senyei allegedly teaches detecting fetal fibronectin. This rejection is respectfully traversed.

**Claims**

Claim 14 recites that the analyte is fetal fibronectin.

**Analysis**

None of Connolly, Hernicz or Senyei teaches or suggests moving a reader head over the surface of a test strip. Thus, when combined, the cited references cannot establish claim 5 as *prima facie* obvious. Accordingly, the combination of Connolly, Hernicz and Senyei cannot establish claim 14, which is dependent from claim 5, as *prima facie* obvious.

**NEW INDEPENDENT CLAIMS ARE FURTHER PATENTABLE OVER THE CITED ART**

Independent claims 19 and 20 are directed to methods for reading a surface of a test strip, which include steps of moving a reader head to a first position over the surface of the test strip, transmitting light onto the surface at an angle normal to the surface, and measuring light reflected normally from the surface. None of the cited references teach or suggest transmitting light onto the surface of a test strip at an angle normal to the surface. Further, none of the cited references teach or suggest measuring light reflected normally from the

**USSN 09/717,478  
ANDERSON *et al.*  
AMENDMENT AND RESPONSE**

surface. Accordingly, new independent claims 19 and 20 also are novel and unobvious over the combination of teachings of the cited references.

\* \* \*

In view of the above remarks and the amendments and remarks of record, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,  
**HELLER EHRMAN WHITE & MCAULIFFE LLP**

By: 

Stephanie Seidman  
Registration No. 33,779

Attorney Docket No. 24727-813C

**Address all correspondence to:**

**HELLER EHRMAN WHITE & MCAULIFFE LLP**  
4350 La Jolla Village Drive  
San Diego, CA 92122-9164  
Telephone: 858 450-8400  
Facsimile: 858 587-5360  
EMAIL:sseidman@HEWM.com



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Anderson *et al.*

Serial No.: 09/717,478

Filed: November 20, 2000

For: **POINT OF CARE DIAGNOSTIC SYSTEMS**

Art Unit: 1641

Examiner: Davis, D.

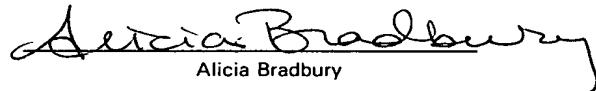
### CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"Express Mail" Mailing Label Number  
EL870637621US

Date of Deposit August 22, 2002

I hereby certify that this paper and the attached papers are being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 C.F.R. §1.10 on the date indicated above and addressed to:

U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

  
Alicia Bradbury

### **ATTACHMENT TO THE AMENDMENT MARKED UP PARAGRAPH AND CLAIMS (37 C.F.R. § 1.121)**

#### **IN THE SPECIFICATION**

Please amend the specification as follows:

**Please amend the paragraph on page 67, lines 7-11 as follows:**

An alternative embodiment of the test device is shown in FIG. 2B. The components of device are shown in FIG. 3 and include the upper and lower members 302 and 304 of the housing and the test strip 100. Also shown are the sample application port 306, test window 308, and the optionally included bar code 316. Also shown are an aperture 306 above the detection and control zones, the upper surface 308 of upper member 302, an end 310 used for gripping the housing, and a sample window 312.

#### **IN THE CLAIMS**

Please amend claims 1-3, 5-6, 9, 11 and 13-14 as follows:

1. (Amended Twice) A method for reading [the] a surface of a test strip comprising an image, comprising:

[scanning] moving a reader head in a [reflectence] reflectance reader [of] to a first position over the surface comprising the image;

[determining] measuring a first amount of light reflected from the surface comprising the image;

USSN 09/717,478  
ANDERSON *et al.*  
AMENDED CLAIMS

uniformly illuminating the surface with light of a first wavelength, and  
[determining] measuring a second amount of light reflected from the surface;  
and

uniformly illuminating the surface with light of a second wavelength, and  
[determining] measuring a third amount of light reflected from the surface[; and  
determining a parameter correlated with [the] an intensity or shape of the  
image].

2. (Amended Twice) The method of claim 1, wherein the [reader is a  
reflectance reader with a] reader head [that] comprises:

    a reader head body;  
    a light emitting diode;  
    a first fiberoptic bundle optically coupled to the light emitting  
    diode;  
    a photodetector;  
    a second fiberoptic bundle optically coupled to the  
    photodetector;  
    an aperture in the reader head body; and  
    a plurality of fiberoptic conductor ends arranged in a  
    sigmoidal distribution in the aperture, wherein: a first portion of the  
    fiberoptic conductor ends comprises fiberoptic conductors of the  
    first fiberoptic bundle; and a second portion of the fiberoptic  
    conductor ends comprises fiberoptic conductors of the second  
    fiberoptic bundle.

3. (Amended) The method of the claim 1, wherein the reflectance reader  
further comprises,

    a control unit including a processor modified with a software subsystem,  
    wherein the software subsystem is for analyzing [the] data produced in the  
    [test] steps of determining the first, second and third amounts of light reflected  
from the surface.

USSN 09/717,478

ANDERSON *et al.*

AMENDED CLAIMS

4. (Amended) The method of claim 1, [wherein the method comprises] further comprising performing an immunoassay [is performed] on the test strip.

5. (Amended Three Times) The method of claim 1, wherein the [reader is] a] reflectance reader[, comprising] comprises:

[a] the reader head comprising:

    a reader head body;

    a light emitting diode;

    a first fiberoptic bundle optically coupled to the light emitting diode, and adapted to transmit light from the light emitting diode;

    a photodetector adapted for generating a reflection signal in response to reflected light;

    a second fiberoptic bundle optically coupled to the [light] photodetector, and adapted to transmit an amount of reflected light to the photodetector;

    an aperture in the reader head body; and

    a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic conductor ends comprises fiberoptic conductors of the second fiberoptic bundle, the plurality of fiberoptic conductor ends being further arranged in a substantially co-planar relationship; and a reader housing comprising:

    a housing body; and

    a cassette slot adapted to receive a test device.

6. (Amended) The method of the claim 5, wherein the reflectance reader further comprises,

    a control unit including a processor modified with a software subsystem, wherein the software subsystem is for analyzing [the] data produced [in the

USSN 09/717,478

ANDERSON *et al.*

AMENDED CLAIMS

test] from the steps of determining the first, second and third amounts of light reflected from the surface.

7. (Amended) The method of claim 5, [wherein the method comprises] further comprising performing an immunoassay [is performed] on the test strip.

8. (Amended) The method of claim 1, further comprising determining a parameter correlated with the intensity or shape of the image, wherein the parameter is the amount of an analyte in a sample, which is a function of the first amount of light reflected, the second amount of light reflected, and the third amount of light reflected.

9. (Amended) The method of claim 1, wherein the method [is for] further comprises determining an amount of an analyte in a sample by correlating the [reading] parameter with the amount of analyte in the sample.

11. (Amended Twice) The method of claim 1, wherein said first wavelength is selected to reflect [substantially] equally from all regions of the test strip, whereby said second amount of light is indicative of a test region of test strip.

12. (Amended Twice) The method of claim 1, wherein said second wavelength [is selected to reflect] reflects substantially optimally from a test region of the test strip, whereby said third amount of light is indicative of an amount of a label at the test region.

13. (Amended) The method of claim 1, further comprising determining an amount of an analyte in a sample, wherein the analyte is fetal fibronectin.

14. (Amended) The method of claim 5, further comprising determining an amount of an analyte in a sample, wherein the analyte is fetal fibronectin.



Approved  
J.T.W.  
11-13-02

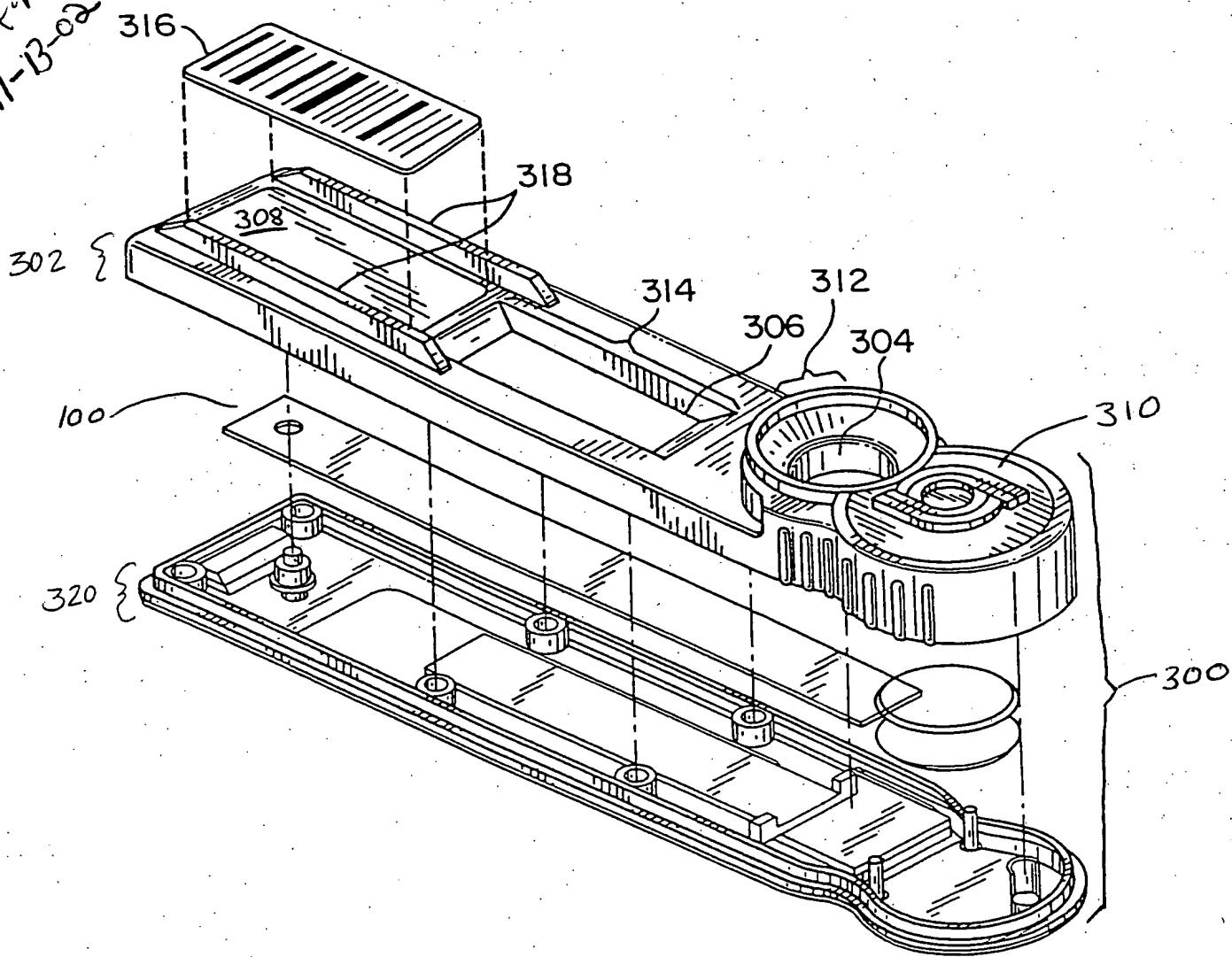


FIG. 3